

Docket No: 515-4218

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT OPERATIONS

In re Application of:

**Achille Arini et al.**

Serial No.: 09/815533

Filed: March 16, 2001

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) Group Art Unit:  
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) Examiner:  
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For: **METHOD FOR THE PRODUCTION OF PHARMACEUTICALLY  
ACTIVE RECOMBINANT PROTEINS**

New York, N.Y. 10036  
April 23, 2001

Commissioner For Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

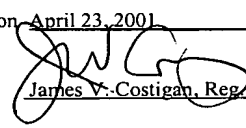
SIR:

Request is hereby made for consideration of this information disclosure statement.  
The following references are being cited under the provisions of § 1.97.

I hereby certify that this correspondence is being deposited with  
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Commissioner for Patents  
Washington, DC 20231

on April 23, 2001

  
James V. Costigan, Reg. No. 25,669

EP 0 154 272 B1

Discloses the production of urokinase using recombinant DNA techniques which involve recovering mRNA from human kidney cells, preparing cDNA, inserting into a vector and introducing the resulting plasmid into an animal cell.

EP 0 303 028 A1

Discloses a method for preparing single chain urokinase by recovering the prourokinase gene from human cells, inserting into a vector and introducing the plasmid into an animal cell.

DE 3439 980 A1

Discloses a procedure for purifying and pasteurization of urokinase where the product can be used for therapeutic purposes.

DT 25 51 017 A1

Discloses a procedure for the production of urokinase.

#### NONPATENT LITERATURE

“Urinary and Kidney Cell Plasminogen Activator”, G.H. BARLOW, *In Scrip's Thrombolytic Report*, pp. 239-245.

Describes urokinase assay methods using the Clot Lysis method and the Esterolytic method. Describes a purification methodology from urine or media and properties of urokinase.

“Plasminogen and Plasmin”, K.C. ROBBINS & L. SUMMARIA, *In Scrip's Thrombolytic Report*, pp. 257-273.

Describes plasminogen/plasmin specificity and assay methods, nomenclature, method of isolation, isoelectric focusing, activation/inhibition and properties.

“N-Linked Carbohydrate Chains From Human Urokinase”, A.A. BERGWERFF, 228 Eur. J. Biochem., 1009-19 (1995).

Describes the primary structure of the major N-linked carbohydrate chains attached to urinary-type plasminogen activator (urokinase).

“High Level Expression of Human Prourokinase cDNA in Chinese Hamster Ovary Cells”, C. DUSHENG et al., 9(3) Chinese J. Biotech. 151-158 (1994).

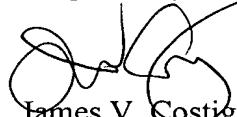
Describes the expression of high levels of human prourokinase gene CDNA in Chinese hamster ovary cells, construction of good expression vector, improved transfection technique and gene co-amplification.

“Abbott Abbokinase Use Should be Limited Due to Infection Risks From Donors”, F-D-C REPORTS, THE PINK SHEET, February 1, 1999, p.6.

Discusses the FDA “Dear Doctor” letter of 1/25/99 pertaining to the risk of infectious disease transmission from Abbokinase®.

A copy of each of the above references is enclosed.

Respectfully submitted,

  
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